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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,296	12/12/2005	Pengcheng Li	034176 R 004	3215

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,296	LI ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 2/20/2009 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claim 1 has been canceled.

2. Remarks drawn to rejections under 35 USC 103.

Claims 2-12 are pending in the case.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of Claims 2-12 under 35 U.S.C. 103(a) as being unpatentable over Li et al (Chinese Journal of Biochemical Pharmaceutics, 2002, 23(3), 132-33; cited in IDS of 2/17/06) in view of Yokota (JP 63-182304) and Kolupavev, et al (Fizilogia I Biokhimiya Kul'turnykh Rastenii, 1991, 23(3), 267-74; English Abstract) is being maintained for reasons of record.

Li et al teach that microwave irradiation is known to be used in the rapid and easy preparation of water-soluble chitosan oligosaccharides in an aqueous solution (see English Abstract). The process took three minutes to give a high yield of the oligomer. Li et al. further teach that microwave irradiation may be possibly used in other field of chitosan modification.

Li et al do not expressly teach or suggest the irradiation of chitosan in the presence of an electrolyte such as adding NaCl into in the preparation as instantly claimed.

Yokota teaches the hydrolysis of chitosan in the presence of hydrochloric acid (an electrolyte; see English abstract).

Moreover, NaCl (an electrolyte) is known to be intense hydrolysis of oligosaccharides, or to increase or assist the hydrolysis of oligosaccharides according to Kolupaev et al. (see abstract in English).

It would have been obvious to one of ordinary skillinthe art at the time the invention was made to make chitosan oligomers via degradation of chitosan by microwave irradiation in the presence of an electrolyte since the such a method using electrolyte and microwave individually are seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to use microwave irradiation for the hydrolysis of chitosan since microwave irradiation is known to accelerate and simplify the hydrolysis reaction of chitosan according to Li. Moreover, adding NaCl to the hydrolysis since it is known that NaCl can increase or assist the hydrolysis of oligosaccharides according to Kolupaev et al.

Furthermore, one of ordinary skill in the art would have recognized that using an electrolyte like hydrochloric acid or NaCl would be to avoid oxidative side reactions or further oxidative degradation of the chitosan oligomers by a strong oxidant such as peroxide employed by Li. One of ordinary skill in the art also knows that handling hydrogen peroxide can be dangerous. Substitution of peroxide with a mild electrolyte like hydrochloric acid or NaCl or other similar electrolytes is also safer.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Response to Applicants Arguments

Applicants have traversed the above rejection of record arguing that:

1. The reaction according to the present invention is a homogenous reaction which is not taught or suggested by the prior art. In particular the prior art does not teach or suggest the use of dilute hydrochloric acid and another electrolyte to increase the speed of degradation.

2. Li's (In this reference Li is the last named inventor and Ying-hong Dang is the first inventor. The English translation mentions the first named inventor) reaction is heterogeneous and the peroxide that Li uses is not the same as the electrolyte as used instantly.

3. Yokota also relates to a heterogeneous reaction using a system consisting of alcohol, water and hydrochloric acid. The acid was used to only slightly degrade chitosan in traditional conditions, which are not the conditions set forth in the instant process.

4. Kolupaev discloses sublethal concentration of NaCl induced intense of hydrolysis of oligosaccharides in the presence of enzyme. There is no teaching of hydrolysis of polysaccharides like chitosan. One of ordinary skill in the art would not expect that NaCl will degrade chitosan with a reasonable expectation of success.

Applicants' arguments have been considered but are not found to be persuasive.

Li et al teach that microwave irradiation is known to be used in the rapid and easy preparation of water-soluble chitosan oligosaccharides in an aqueous solution (see English Abstract and Translation. In this reference Li is the last named inventor and Ying-hong Dang is the first inventor. The English translation mentions the first named inventor). The process took three minutes to give a high yield of the oligomer with the microwave power at about 400W. Li et al. further teach that microwave irradiation may be possibly used in other field of chitosan modification. The fact that Li et al do not expressly teach or suggest the irradiation of chitosan in the presence of an electrolyte such as adding NaCl in the preparation was acknowledged in the previous action. The instant claims do not specifically recite that the process is homogeneous. Even if applicants intend a homogeneous system applicants have not shown that the said degradation does not proceed at all with heterogeneous system. There is no such teaching or suggestion in the prior art either. According to Li (same as Ying-hong Dang et al) the results presented in Table 3 (see page 6 of translation) the molecular weight of the chitosan decreases with increasing power and chitosan of various molecular weights under different conditions can

be prepared based on molecular weight requirements. This means that the conditions can be chosen such that chitosan having molecular weights in the range as instantly claimed can be prepared with a reasonable expectation of success.

Yokota teaches the hydrolysis of chitosan in the presence of hydrochloric acid (an electrolyte; see English translation; Claims 2 and 5 at page 2) and also the range of concentrations for the acid with respect to the chitosan (page 3, top). It is well known to one of ordinary skill in the art that hydrochloric acid is also an electrolyte. Yokota teaches degradation of chitosan via hydrolysis by applying heat (page 7 last paragraph through page 8, middle). One of ordinary skill in the art also knows that application of microwave to a system releases heat energy. So, if hydrochloric acid can degrade chitosan to low molecular weight chitosan by applying heat via a traditional method it should also degrade chitosan when heated by microwave.

NaCl (an electrolyte) is known to increase or assist the hydrolysis of oligosaccharides according to Kolupaev et al. (see abstract in English and translation, page 15, first full paragraph). One of ordinary skill in the art will recognize that such assistance to hydrolysis of chitosan (which leads to low molecular weight chitosan via breakage of the links between the monomeric units) can be expected in the instant method with a reasonable expectation of success since an analogous electrolyte (HCl as taught by Yokota) does it.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make chitosan oligomers via degradation of chitosan by microwave irradiation in the presence of an electrolyte since a method for preparation of low molecular weight chitosan using an electrolyte and microwave individually are taught in the prior art.

One of ordinary skill in the art would be motivated to use microwave irradiation in the presence of electrolytes like HCl, NaCl, etc., for the hydrolysis of chitosan since microwave irradiation is known to accelerate and simplify the hydrolysis reaction of chitosan according to Li. Adding NaCl to the hydrolysis mixture is known to increase or assist the hydrolysis of oligosaccharides according to Kolupaev et al.

Furthermore, one of ordinary skill in the art would have recognized that using an electrolyte like hydrochloric acid or NaCl would be to avoid oxidative side reactions or further oxidative degradation of the chitosan oligomers by a strong oxidant such as peroxide employed by Li. One of ordinary skill in the art also knows that handling hydrogen peroxide can be dangerous. Substitution of peroxide with a mild electrolyte like hydrochloric acid or NaCl or other similar electrolytes is also safer. Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art. Adjusting the concentrations, reaction times, microwave power, etc., in order to get chitosan with the desired molecular weight is well within the skill level of the artisan. Such is also suggested in the prior art.

Conclusion

Claims 2-12 are rejected

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ganapathy Krishnan/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623